3 Setup and Tests

Setup of the AEM Monitoring System (Monopolar)

MOUNTING:

Mount the AEM Monitor under the electrosurgical generator so the adapter cable reaches the return electrode connector. The AEM Monitor is supplied with feet spaced for compatibility with most equipment carts. Recesses are provided in the cover of the AEM Monitor so most specified electrosurgical generator products may be located securely upon it.

Warning

ELECTRICAL SHOCK HAZARD. CONNECT THE POWER CORD TO A PROPERLY GROUNDED RECEPTACLE. DO NOT USE POWER PLUG ADAPTERS.

FIRE HAZARD. DO NOT USE EXTENSION CORDS.

ELECTRICAL SHOCK HAZARD. DO NOT CONNECT WET ACCESSORIES TO THE GENERATOR. ENSURE THAT ACCESSORIES AND ADAPTERS ARE CORRECTLY CONNECTED AND THAT NO METAL IS EXPOSED.

DO NOT ATTEMPT TO CONNECT OR DISCONNECT ANY CABLE DURING POWER ACTIVATION.

Caution

INSPECT ACCESSORIES AND CORDS FOR BREAKS, CRACKS, NICKS OR OTHER DAMAGE BEFORE EVERY USE. INSURE THAT END OF LIFE INDICATORS ARE NOT PRESENT. IF ANY OF THESE ARE PRESENT, DO NOT USE. FAILURE TO OBSERVE THIS PRECAUTION MAY RESULT IN INJURY OR ELECTRICAL SHOCK TO THE PATIENT OR OPERATING PERSONNEL.

CONFIRM PROPER POWER SETTINGS BEFORE PROCEEDING WITH SURGERY. USE THE LOWEST POWER SETTING POSSIBLE FOR THE MINIMUM TIME NECESSARY TO ACHIEVE THE DESIRED SURGICAL EFFECT.

POWER CORD:

Caution

CONNECT THE POWER CORD TO A WALL OUTLET HAVING THE CORRECT VOLTAGE. OTHERWISE PRODUCT DAMAGE MAY RESULT.

1. Connect the AEM Monitor power cord to a wall receptacle with the proper voltage.

SELF-CHECK:

2. Turn on the AEM Monitor. The system completes an automatic self-check. All of the visual indicators illuminate and two beeps are heard. If this is not the case, please refer to the troubleshooting section.

Caution

DO NOT USE THE AEM MONITOR UNLESS THE SYSTEM PROPERLY COMPLETES THE AUTOMATIC SELF-CHECK. OTHERWISE, AEM FUNCTIONS MAY NOT BE OPERATIVE.

INHIBIT ADAPTER:

Notice

THE FOLLOWING REQUIRES THAT THE ELECTROSURGICAL GENERATOR MEET THE CONTACT RESISTANCE CRITERIA. REFER TO THE INSTRUCTIONS FOR THE ELECTROSURGICAL GENERATOR.

3. Connect the AEM Monitor inhibit adapter to the return electrode receptacle of the electrosurgical generator having compatibility with the AEM system.

4. Connect a return electrode to the AEM Monitor inhibit adapter. Verify the amber return electrode light turns off.

AEM CORD ADAPTER:

Warning

DO NOT TOUCH CENTER PIN OF AEM CORD ADAPTER DURING SET UP. IT MAY BE ACTIVE IF SETUP INSTRUCTIONS ARE NOT CORRECTLY FOLLOWED.

5. Plug the cylindrical end of the AEM Cord Adapter into the ESU; plug the other end into the AEM Cord receptacle on the AEM Monitor.

6. Connect an AEM Cord with an AEM instrument to the AEM Cord Adapter at the ESU.

7. Verify that the amber AEM Cord light turns off and the green ***Ready*** light is on.

8. Turn on the electrosurgical generator and enable its contact quality monitoring system. It should be in its normal operational state.

After successful completion of these steps the AEM Monitor is ready for use.

Optional Functional Test for Operating Room (before procedure begins)

An optional test to verify proper function and integrity of the instruments is described below. This test verifies that AEM interment's internal insulation is in good condition and can be expected to perform without alerts during surgery.

1. Apply the return electrode to the patient.

2. Set the electrosurgical generator to “coag spray” or “coag fulgurate” (the highest voltage mode depending upon the generator) and set up the power level to 80 W (50 W with ConMed/Aspen Excalibur spray).

3. Next, in the sterile field,
   - ❏ Connect the instrument to the AEM Cord, so that the tip does not touch any other object.
   - ❏ Key the generator using the foot switch for approximately 3 seconds.
   - ❏ Verify that the power indicator on the generator does illuminate and that there are no AEM Monitor alerts.
   - ❏ Repeat this test on each AEM instrument.

4. Reset the power setting to the normal level.

5. Do not return any instrument giving an alert to the tray, but instead discard it or isolate it for further study. Record the type of AEM Monitor alert given: “Insulation Fault” or “AEM Cord”.

   Note: In the case of cord alert, the fault may be in the cord itself, the AEM Cord Adapter, or in the contact of the instrument.

Checking the Monitoring System (Monopolar)

The following is a quick test of the AEM Monitoring System. A failure on any of the following tests should be resolved before use of the system. Please refer to the troubleshooting section to establish the cause of any failure. Encision recommends that this test be performed once per year.

Power On Self Test Function (POST)

1. POST is activated when the power is switched on after being off for at least 30 seconds. In POST, each of the monopolar visual indicators is illuminated for 6 seconds and two beeps are heard.

AEM Cord Connect and Disconnect

Notice

THIS TEST REQUIRES THAT THE ELECTROSURGICAL GENERATOR MEET THE CONTACT RESISTANCE CRITERIA. REFER TO THE INSTRUCTIONS FOR THE ELECTROSURGICAL GENERATOR.

2. Connect the AEM Monitor inhibit adapter into the return electrode receptacle of the electrosurgical generator with a contact quality monitoring system .

3. Connect a return electrode to the AEM Monitor inhibit adapter.

4. Plug the cylindrical end of the AEM Cord Adapter into the ESU; plug the other end into the AEM Cord receptacle on the AEM Monitor.

5. Connect an AEM cord with an AEM instrument to the ***AEM Cord Adapter*** at the ESU.

6. Verify that the alarm indicators are off and the ***Ready*** indicator illuminates on the AEM Monitor.

7. Turn on the electrosurgical generator and enable its contact quality monitoring system. It should be in its normal operational state.

8. Disconnect the AEM cord from the ***AEM Cord Adapter*** at the ESU. Verify that the following occurs:

   - ❑ AEM Monitor ***AEM Cord*** indicator illuminates
   - ❑ AEM Monitor ***Ready*** indicator extinguishes
   - ❑ The contact quality monitoring system on the electrosurgical generator alarms

9. Reconnect the AEM cord to the ***AEM Cord Adapter*** at the ESU. Verify that the following occurs:

   - ❑ The AEM Monitor ***AEM Cord*** indicator extinguishes
   - ❑ The AEM Monitor ***Ready*** indicator illuminates
   - ❑ The contact quality monitoring system on the electrosurgical generator no longer alarms

Return Electrode Connect and Disconnect

10. Verify that the alarm indicators are off and the ***Ready*** indicator illuminates on the AEM Monitor.

11. Disconnect the return electrode from the AEM Monitor inhibit adapter. Verify that the following occurs:

    - ❑ The AEM Monitor ***Return Electrode*** indicator illuminates
    - ❑ The AEM Monitor ***Ready*** indicator extinguishes
    - ❑ The contact quality monitoring system on the electrosurgical generator alarms

12. Reconnect the return electrode from the AEM Monitor inhibit adapter. Verify that the following occurs:

- ❑ The AEM Monitor ***Return Electrode*** indicator extinguishes
- ❑ The AEM Monitor ***Ready*** indicator illuminates
- ❑ The contact quality monitoring system on the electrosurgical generator no longer alarms

Active Electrode Spark to Shield Connector

13. Connect a miniature alligator clip between the two pins of the AEM Monitor ***AEM Cord*** receptacle.

14. Connect a pencil electrode to the electrosurgical generator with a contact quality monitor. Verify that the following occurs:

    - ❑ The AEM Monitor alarm indicators are extinguished
    - ❑ The AEM Monitor ***Ready*** indicator illuminates
    - ❑ The electrosurgical generator, with the contact quality monitoring system enabled, is in its normal operating state.

15. Set the electrosurgical generator with the contact quality monitoring system to 20 watts in the standard coagulation mode.

16. Activate the electrosurgical generator and touch the alligator clips with the pencil electrode. Verify that the following occurs:

    - ❑ There is a visible spark at the active electrode
    - ❑ The AEM Monitor ***Ready*** indicator extinguishes for ten seconds
    - ❑ The AEM Monitor ***Insulation*** indicator illuminates for thirty seconds
    - ❑ The contact quality monitoring system on the electrosurgical generator alarms
    - ❑ The AEM Monitor alarms

Setup of the Endpoint Monitor System (Bipolar)

Notice

IF YOU ARE USING THE ENCISION ENDPOINT MONITOR REMOTE DISPLAY (EMR), MOUNT THE DISPLAY NEAR THE VIDEO MONITOR OR AT ANOTHER LOCATION IN THE VIEW OF THE OPERATING ROOM STAFF.

IF BOTH BIPOLAR AND MONOPOLAR FUNCTIONS ARE BEING USED ,THE MONOPOLAR INSTRUMENT MUST REMAIN CONNECTED TO AVOID SPURIOUS ALARMS.

Caution

When using the Encision Endpoint Monitor Remote Display, only the remote illuminates during bipolar current flow. The Endpoint Monitor front panel on the Encision Monitoring System does not illuminate.

1. Plug one end of the **Bipolar Jumper Cable** into the vertical pair of jacks on the AEM Monitor labeled BIPOLAR GENERATOR, the other end into the ESU bipolar output jacks.

Warning

Electrical Shock Hazard. Accessible pins of the jumper cord may lead to shock or burns to surgical personnel, if the generator bipolar output is activated while the bipolar cord is plugged into the generator receptacle, but the other end is not plugged into the AEM Monitor receptacle.

Electrical Shock Hazard. Do not connect wet accessories to the generator. Ensure that accessories and adapters are correctly connected and that no metal is exposed.

Caution

Inspect accessories and cords for breaks, cracks, nicks or other damage before every use. Insure that end of life indicators are not present. If any of these are present, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or operating personnel.

2. Prepare the surgical instrument to be used for the procedure. Connect one end of the bipolar instrument cord to the instrument and the other end into the ***Bipolar Accessory*** receptacle on the left front panel of the AEM Monitor.

3. Adjust the volume of the clicks that indicate bipolar current flow. The ***Volume Control*** switch is located on the left **rear** panel of the AEM Monitor.

Caution

The Endpoint Monitor activation clicks when an accessory is active. Do not turn the volume down to where the clicking sound is below an audible level.

4. Adjust the bipolar output mode and power setting.

Caution

Confirm proper power settings before proceeding with surgery. Use the lowest power setting possible for the minimum time necessary to achieve the desired surgical effect.

5. After successful completion of these steps, the bipolar activation tone on the bipolar generator sounds and the system is ready for operation. In operation, the bipolar indicator bar illuminates, indicating the current flowing between tines.

Warning

DO NOT ATTEMPT TO CONNECT OR DISCONNECT ANY CABLE DURING POWER ACTIVATION.

Checking the Endpoint Monitoring System (Bipolar)

The response of the Endpoint Monitor may be tested during use.

1. Set the generator at 5 to 10 watts (depending upon the generator characteristics).

2. Touch the tines of the instrument together. There should be a smooth registration of the current on the bar-graph scale. The clicking will also change its rate in correspondence with the current.

When performing this check for the first time with a particular bipolar generator, start at a low setting, then increase the setting to obtain a mid scale deflection of the bar-graph. This test ensures that all three components (cord, bipolar instrument and Endpoint Monitor) are functional.

Mechanical Inspection

The AEM Monitor and Endpoint Monitor require minimal maintenance. It is recommended that the AEM Monitor be inspected by qualified service personnel at least twice a year. This inspection should include the list below. Periodically, the following list should be checked.

Warning

ELECTRICAL SHOCK HAZARD. GROUND NUT MUST BE SECURE.

- ❑ Ground nut properly secured to ground post.
- ❑ No evidence of damage on insulation of wiring and cable.
- ❑ Connectors and cables are fully seated.
- ❑ All hardware is securely fastened.
- ❑ AEM Monitor / Endpoint Monitor system check.

Electrical Inspection

Verification of the Endpoint Monitor display. Encision recommends that this test be performed once per year.

1. Connect the Endpoint Monitor to any compatible electrosurgical generator with a continuously adjustable output (not digital) in series with a noninductive load resistor between 50 ohms and 200 ohms and a reference meter.
2. The reference meter would have a true RMS response, a band width of at least 10 MHz and an accuracy of 1%.

3. Agreement between the Endpoint Monitor and the reference meter should be within 10% of full scale with currents between 600 mA and 1000 mA.

Cleaning

Warning

ELECTRIC SHOCK HAZARD. ALWAYS UNPLUG THE AEM MONITOR BEFORE CLEANING.

(NOTE: CLEAN MONITOR WHEN NEEDED.)

1 Turn off the AEM Monitor.

2 Disconnect all accessories.

3 Follow the procedures approved by your institution or use a validated infection control procedure.

4 Use a mild cleaning solution or disinfectant and a damp cloth to thoroughly wipe all outside surfaces and the power cord.

Notice

DO NOT ALLOW FLUIDS TO ENTER THE CHASSIS.

DO NOT CLEAN THE AEM MONITOR WITH ABRASIVE CLEANING OR DISINFECTANT COMPOUNDS, SOLVENTS, OR OTHER MATERIALS THAT COULD SCRATCH THE PANELS OR DAMAGE THE UNIT.

DO NOT STEAM STERILIZE THE AEM MONITOR.

Storing the AEM Monitor

The AEM Monitor should be stored within these temperatures and humidities:

Temperature: -13 to 158 F (-25 to 70 C)

Humidity: 5% to 95% relative, noncondensing

If you store the AEM Monitor at a temperature that is outside its normal operating range of 50 to 122 F (10 to 50 C), allow one hour for the monitor to reach room temperature before use.

Service Center

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